



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/806,327 | 03/22/2004 | Yi Feng Zheng | 7456 | 1742 |

34500 7590 06/01/2005

DADE BEHRING INC.
LEGAL DEPARTMENT
1717 DEERFIELD ROAD
DEERFIELD, IL 60015

EXAMINER

HAQ, SHAFIQL

| | |
|----------|--------------|
| ART UNIT | PAPER NUMBER |
|----------|--------------|

1641

DATE MAILED: 06/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/806,327 | ZHENG ET AL. | |
| | Examiner | Art Unit | |
| | Shafiqul Haq | 1641 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-47 is/are pending in the application.
- 4a) Of the above claim(s) 28-47 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-27 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>4/22/04</u> . | 6) <input type="checkbox"/> Other: ____ |

Handwritten signature/initials

DETAILED ACTION

Status of Claims

1. Claims 1-47 are pending in the application. Claims 28-47 are withdrawn from further consideration pursuant to 37 C.F.R. 1.142 (b) as being drawn to a non-elected subject matter.

Election/Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-27 drawn to a compound comprising amphetamine and methamphetamine, classified in class 564 and subclass 336.
 - II. Claims 28-47, drawn to a method and kit for determining amphetamine and methamphetamine in a sample, classified in class 435, subclass 7.1.

The above groups represent general areas wherein the inventions are independent and distinct, each from the other because of the following reasons:

3. Inventions of group I and group II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product of group I can be used in a materially different process such as purifying target antibody.
4. All compounds falling outside the class(es) and subclass(es) of the selected compound and any other subclass encompassed by the election above will be

Art Unit: 1641

directed to nonelected subject matter and will be withdrawn from consideration under 35 U.S.C. 121 and 37 C.F.R. 1.142(b). Applicant may reverse the right to file divisional applications on the remaining subject matter. (The provisions of 35 U.S.C. 121 applies with regard to double patenting covering divisional applications.)

5. During a telephone conversation with Theodore J. Leitereg on 5/23/05 a provisional election was made without traverse to prosecute the invention of Group I, claims 1-27. Affirmation of this election must be made by applicant in replying to this Office action. Claims 28-47 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.
6. Applicant is reminded that upon cancellation of claims to a nonelected invention, the inventions must be amended in compliance with 37 C.F.R. 1.48(b) if one of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 C.F.R. 1.48(b) and by the fee required under 37 C.F.R. 1.17(i).

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Although specific claims may be discussed in the rejections below, these rejections are also applicable to all other claims in which the noted problems/language occur.

Art Unit: 1641

9. Claims 1-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
10. In claims 1, 5 and 11 it is unclear what the chemical nature and scope of the term "linking group". The point of attachment of the "second linking group" to the "first linking group" is also unclear.
11. Claim 1 is vague and indefinite as the exact configuration of the "compound" is unclear. The claim recites the term "the distance" in line 3 and is not clear whether "the distance" is in terms of number of molecules or in terms of manometers. It is also unclear what is meant by the term "depends" in line 2. Does this term mean "linked to"? If it is linked to the first linking group, the exact nature of the linkage is unclear.
12. Claim 4 recites the term "stereospecific" in line 2. It is not clear what does this mean? Specific to what?
13. With respect to claim 5, it is not clear how the different moieties are attached to each other (i.e. point of attachment of A to L, M to L, Y to L and Y to Z).
- The claim recites the term "Y is a bond, a functional group". The term "functional group" implies a terminal position and Y is a non-terminal group. It is not clear how Y can be a functional group. It is not clear what is encompassed by the terms "poly(amino)" and "non-poly(amino)" label moiety.
14. Claim 6 language is confusing and it is not clear what is meant by the term "same position".

Art Unit: 1641

15. With respect to claims 7, 12, 16 and 22 it is not clear what is encompassed by the term enzyme as the term "enzyme" is a general term which may encompass enzymes that fall into different classes and subclasses.
16. Claims 11, 15, 21 and 25 recite the term "protecting group". It is not clear what is encompassed by this term because "protecting group" is a general term which includes numerous groups for protection of functional groups -OH, -NH, -SH, -COOH and -CO. Therefore, the claims are vague and indefinite for not clearly defining the protecting group.
17. With respect to claims 15 and 21, it is not clear what is it connected to when the variable "Z" is "a bond".
18. In claims 22-25 at line 1, the variables R_1 and R_2 need to be corrected in order to avoid insufficient antecedent basis because the claims depend from claim 21 which recites R_1' and R_2' .
19. With respect to claims 23-24, "s" cannot be "0" since the claim depends from claim 21 wherein "s" is "1 to 5".
20. With respect to claims 5, 11, 15, 21 and 26 it is unclear how the multiple structures are linked to one another.
21. With respect to 5, 11, 15, 21 and 26, it is not clear what is "t" for other condition?
22. With respect to 5, 11, 15, 21 and 26, the definition of "Z" is confusing. "Z" is first defined as "a poly(amino acid)or a functional group" and later defined as "an integer between 1 divided by about 500". This definition is confusing and unclear and thus the claims are indefinite.

Art Unit: 1641

23. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-27 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for specific linking groups and configurations as set for the in working examples, is however, not enabling for the entire scope encompassed. The specification provides guidance for use of acetamido and alkylene group (see page 5, formula IV of the specification) as linking group, but there in no enablement in the specification for use of all other linking groups such as phosphodiester or peptide.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. .


Conclusion


24. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shafiqul Haq whose telephone number is 571-272-6103. The examiner can normally be reached on 7:30AM-4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1641

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


SHAFIQL HAQ
EXAMINER
ART UNIT 1641


MARY E. CEPERLEY
PRIMARY EXAMINER
ART UNIT 1641